



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JAN 29 1997

Mr. Christopher Jensen
Director, Health Sciences
Shaklee Technica
Shaklee Terraces
444 Market Street
San Francisco, California 94111-5325

Dear Mr. Jensen:

This is in response to your letter of December 19, 1996 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making the following statement for your product, Premium Garlic.

A variety of studies have shown that daily intake of garlic may help lower blood cholesterol levels.

This claim does not come within the coverage of section 403(r)(6) of the act. We would point out that section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to prevent, treat, or mitigate heart disease, in that it claims that "daily intake of garlic may help lower blood cholesterol levels." A product that claims to lower cholesterol, but is not used in the context of dietary management, is a drug within the meaning of section 201(g)(1)(B) of the act, and is subject to regulation under the drug provisions of the act. If you intend to make a claim of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

James Tanner, Ph.D.
Acting Director,
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

97S-0163

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Shaklee Technica
A Division of Shaklee Corporation
Shaklee Terraces
444 Market Street
San Francisco, CA 94111-5325

Telephone 415/954-3000

December 19, 1996

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204

Re: Section 403(r)(6) Notification

Dear Sir/Madam:

In accordance with the requirements of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, Shaklee Corporation notifies FDA that it has begun using the following statements:

A variety of studies have shown that daily intake of garlic may help lower blood cholesterol levels. Used daily, important phytochemicals in Shaklee Premium Garlic may help maintain a healthy cardiovascular system.

which contains the statutory statement, on the following product:

Premium Garlic

I certify that the foregoing is complete and accurate, and that Shaklee Corporation has substantiation that the statements are truthful and not misleading.

Very truly yours,

Christopher Jensen, MS, RD
Director, Health Sciences

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, San Francisco District Office, Office of Compliance, HFR-PA100

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200